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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/879,329

Applicant(s)

SIGNER ET AL.

Examiner

Daniel M. Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 8, 9 and 19-21 is/are allowed.
- 6) ☒ Claim(s) 1-7, 10-16 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 June 2006 has been entered.

This Office Action is a reply to the Paper filed 2 June 2006 in response to the Final Office Action mailed 2 March 2006. Claims 1-21 were considered in the 2 March Office Action. Claim 17 was canceled and claims 1-4, 6, 7 and 10-16 were amended in the 2 June Paper. Claims 1-16 and 18-21 are pending and under consideration.

Response to Amendment and Arguments

Objection to and rejection of claim 17 is rendered moot by the cancellation thereof.

Specification

Objection to the specification is **withdrawn** in view of the amendment of the claims to remove the recitation of a "non-native gene of interest".

Claim Rejections - 35 USC § 112

Rejection of claims 1, 3, 6, 7 and 10-16 under 35 U.S.C. 112, first paragraph, as containing "new matter" is **withdrawn** in view of the claim amendments.

Rejection of claims 1-7, 10-16 and 18 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of the amendment of the claims to remove the indefinite limitation.

Claim Rejections - 35 USC § 103

Claims 1, 4, 6, 10, 12, 14, 15 and 18 **stand rejected** under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* and further in view of Ow, D. (WO 93/01283) for reasons of record and herein below.

As described in the 1 April 2004 Office Action, Bauer *et al.* teaches a genetic construct comprising a positive selectable marker gene and a negative selectable marker gene, different in kind from the positive selectable marker, and direct repeats of a gene of interest that flank the positive and negative selectable marker genes (see especially the paragraph beginning at line 34 in column 3 and the paragraph bridging columns 3-4). With regard to the limitation of the substrate as "complementary to" the selectable marker, Applicant indicates that this relationship is described in paragraph 30 of the specification. Based on the description therein, the limitation is understood to encompass any medium or growth condition that provides for selection by the marker gene. In columns 8-10, Bauer *et al.* contemplates a variety of positive and negative selectable marker genes and media or growth conditions that provide for selection (*e.g.*, inducers of promoters operably linked to nucleic acids encoding toxic gene products for use as negative selectable markers).

Furthermore, in the paragraph bridging columns 10-11, Bauer *et al.* teaches a method of removing a selectable marker comprising transforming cells with the genetic construct disclosed

therein, identifying transformants using the integration marker (*i.e.*, positive selection marker) and then selecting cells that have lost the negative selection marker by culturing in negative selection medium. Thus, Bauer *et al.* teaches a genetic construct having all of the limitations of the genetic construct system of the instant claim 1 and a method having all of the limitations of claim 4 except that Bauer *et al.* does not teach the construct system applied to plants.

Ow teaches a method of producing marker-free transgenic plants wherein a selectable marker gene is flanked by site specific recombination sites and excised using a site specific recombinase (see especially the discussion beginning the first full paragraph on page 6 and continued through the first full paragraph on page 7).

It would have been obvious to one of ordinary skill in the art to substitute the method of Bauer *et al.*, using a construct comprising a positive and negative selectable marker flanked by direct repeats according to the instant claims, for the method of Ow, which utilizes a selectable marker flanked by site specific recombination signals to remove selectable marker genes from plant cells. One would be motivated to modify the teachings of Ow in this way in view of the teaching of Bauer *et al.* that site specific recombination systems are inferior to the method disclosed therein because the site specific recombination does not remove all of the exogenous DNA (see especially column 3, lines 26-28).

Absent evidence to the contrary, one would have a reasonable expectation of success in practicing the method of Bauer *et al.* in plant cells because one of ordinary skill would expect that the homologous recombination required for deletion of the marker genes would operate in plant cells as well as yeast.

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In view of these considerations, the instant claims 1 and 4, as a whole, would have been obvious to one of ordinary skill in the art at the time the invention was made, as would the method of claim 17, which merely recites that the eukaryotic cell is a plant cell.

Finally, claim 18, which limits the cell of claim 17 to one of a variety of species, would also be obvious to one of ordinary skill in the art because Ow teaches that excision of marker genes is generally desirable in any transgenic plant (see especially the third paragraph on page 4) and explicitly contemplates production of marker-free tobacco (see especially Example 2).

For these reasons, the invention of claims 1, 4, 17 and 18 as a whole would be obvious to one of ordinary skill in the art at the time of filing.

With regard to claims 6, 10, 12, 14 and 15, the claims are directed to the genetic construct of claim 1, wherein the positive and negative selectable markers are limited to specific arrangement within the construct with respect to one another (*e.g.*, GI-PS-NS-GI *versus* GI-NS-PS-GI). Claims 14 and 15 are further limited to comprising additional genes of interest flanking the gene of interest present as a direct repeat. As originally discussed in the 1 April Office Action (page 5), although Bauer *et al.* does not explicitly teach any particular configuration of the positive and negative selectable markers, other than that they should be flanked by the direct repeat, the skilled artisan would not expect that the arrangement of the selectable markers within the boundaries of the direct repeat would affect the function of the construct in any way.

A *prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities because one skilled in the art would be motivated by the expectation that compounds of similar structure will have similar function (see *e.g.*, MPEP 2144.09). Thus, it would be *prima facie* obvious to the skilled artisan to use either of the

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configurations of positive and negative selectable markers set forth in the claims. With regard to additional genes of interest, Bauer *et al.* teaches that the constructs might comprise one or several additional genes of interest located outside of the direct repeat sequence (see especially column 4, lines 11-14).

Given these teachings, the invention of claims 6, 10, 12, 14 and 15, as a whole, would also have been obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

In the remarks filed with the 2 June Paper, Applicant contends that the amended claims would not be obvious because the limitation “two direct repeats of a gene of interest from an organism other than yeast” is not described or suggested by Bauer, which teaches that the direct repeats must be from a yeast strain that belongs to the same genus or same species as the transformed yeast. Applicant further contends that nothing is mentioned in Ow that suggests the use of two direct repeats of a gene of interest from an organism other than yeast.

These arguments have been fully considered but are not deemed persuasive in view of the record as a whole. Applicant is reminded that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As Applicant acknowledges in the Remarks filed 23 December 2005, Bauer *et al.* teaches that the DRS's of the construct should be non-exogenous (p. 7, ¶5 of the 23 December Remarks). As discussed in the 2 March Office Action, the statement cited by Applicant in the 23 December

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remarks, viewed in the context of the Bauer *et al.* as a whole, clearly teaches that by “non-exogenous” Bauer *et al.* means that the DRS sequence should be non-exogenous to the genus or species of organism being transformed. See the paragraph bridging pp. 6-7 of the 2 March Office Action. In view of the fact that the teachings of Bauer *et al.* in view of Ow render obvious practicing the method of Bauer *et al.* in plants (*i.e.*, transforming plants) and in view of the teaching of Bauer *et al.* that the DRS sequence should be non-exogenous to the genus of species of organism being transformed, it would be obvious to one of skill in the art to use plant DRS sequences when practicing the invention in plants. Therefore, limitation of the direct repeats to being from an organism other than yeast does not distinguish the claims from the teachings of the prior art.

Applicant's arguments have been fully considered but are not deemed persuasive in view of the record as a whole; therefore, the claims stand rejected under 35 USC §103(a) as unpatentable over the art.

New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 10-16 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP 2173.05(i) instructs, "Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

In the instant case, independent claims 1 and 4 have been amended to recite that the genetic construct of the claims comprises two direct repeats of a gene of interest "from an organism other than yeast". In support of the amendments, Applicant states that the original specification discloses that direct repeats of a gene of interest may include, but are not limited to, genes which are not normally present in the transformed plants, and may also include any other genes or DNA sequences which are desirable. (Remarks, p. 7, ll. 4-7.) However, even if the disclosure does teach what Applicant asserts, this does not amount to a teaching that yeast sequences should be excluded from the scope of direct repeats of a gene of interest comprised within the genetic construct of the claims. On the contrary, it would seem that such a teaching would indicate that the direct repeats might comprise sequence from any organism. In addition,

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as there is no positive recitation of direct repeats from yeast in the originally filed disclosure at all, there is no basis for explicitly excluding direct repeats from yeast.

For these reasons, limitation of the direct repeats of a gene of interest to being from an organism other than yeast constitutes impermissible new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is indefinite because, due to the cancellation of claim 17, claim 18 now depends from a cancelled claim. There is now no antecedent basis for the "[m]ethod of claim 17" in the claims.

Allowable Subject Matter

Claims 8, 9 and 19-21 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M. Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Daniel M. Sullivan, Ph.D.

Primary Examiner

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